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TITLE: Assessment of Chiropractic Treatment for Low Back Pain, Military Readiness and Smoking Cessation in Military Active Duty Personnel

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14. ABSTRACT This study is comprised of three trials, referred to as the Assessment of Chiropractic Treatment (or ACT). The most significant work during the last reporting period has occurred in the ACT 1 (RCT which is chiropractic for low back pain and smoking cessations) as follows by site. During this reporting period, the most significant research activities were that ACT was initiated in the field as follows: ACT 1 RCT of chiropractic for low back pain in active duty with smoking cessation component is in recruitment phase as follows: Naval Hospital in Pensacola, FL: 38 Allocated (3 enrolled into the Tobacco Cessation nested study) Naval Medical Center in San Diego, CA: 25 Allocated (3 enrolled into the Tobacco Cessation nested study) Walter Reed National Military Medical Center in Bethesda, MD: Anticipated start date – 11MAR2013					
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INTRODUCTION:

Funded by the Office of the Congressionally Directed Medical Research Programs, under contract Number W81XWH-11-2-0107, this study is comprised of three trials, referred to as the Assessment of Chiropractic Treatment (or ACT). The study has the following specific aims:

1. To compare (a) pain and (b) functional outcomes of chiropractic manipulation therapy plus standard care to standard care alone in an RCT of active duty military personnel ages 18-50 with non-surgical acute, sub-acute or chronic low back pain. (ACT1)
2. To measure and compare changes in smoking behavior between the 2 groups. (ACT1)
3. To assess the effect of chiropractic manipulation therapy on military readiness, by comparing pre-post treatment differences in reflexes and reaction times in Special Operation Forces. (ACT2)
4. To determine differences in strength, balance and likelihood of re-injury between combat ready troops receiving either chiropractic manipulation therapy or sham manipulation. (ACT3)

ACT 1-Low back pain RCT with nested smoking cessation study will be conducted at the Walter Reed National Military Medical Center in Bethesda, MD; Naval Hospital in Pensacola, FL; Naval Medical Center in San Diego, CA.

ACT 2-Pre/post differences in reflexes and reaction times in Special Operation Forces will take place at Blanchfield Army Community Hospital, Fort Campbell, KY; and Naval Medical Center in San Diego, CA

ACT 3-RCT of strength, balance and likelihood of re-injury with combat ready troops with chiropractic manipulation therapy compared to sham manipulation will take place at Madigan Army Medical Center, Ft. Lewis McChord, WA.

BODY:

Advisory Board Meeting (ACT 1, TASK 4):

We conducted the second annual Advisory Board Meeting on May 1, 2012. We discussed the progress of the project, the IRB process and challenges, the CRADA process, gave updates on the ACT 2 and ACT 3 protocols, discussed the ACT 1 general meeting held in Las Vegas, medical monitoring, and gave site updates. Further we asked for feedback on the protocols, especially ACT 2 and testing a potential learning effect from taking multiple physical tests. The Board consists of the following members: Dan Cherkin, Ph.D. (CHAIRMAN) of Group Health Research Institute; Scott Haldeman, DC, M.D., Ph.D. of the University of California, Irvine; Scott Haldeman, Consulting Neurology; Valerie Johnson, DC of VAGLA Healthcare System; Wayne B. Jonas, M.D. of Samueli Institute; Anthony J. Lisi, DC of Veterans Health Administration; Dennis Marchiori, DC, Ph.D. of Palmer College of Chiropractic; Marion McGregor, DC, FCCS(C), Ph.D. of Canadian Memorial Chiropractic College; Reed Phillips, DC, Ph.D. of NCMIC Foundation, Inc.; and Thomas V. Williams, Ph.D. of TRICARE Management Activity.

ACT full team meeting (ACT 1, TASK 7):

The first full team meeting including site doctors of chiropractic and study personnel for the Assessment of Chiropractic Treatment (ACT) study was held on March 15, 2012, preceding the annual chiropractic research conference, in Las Vegas, NV. Team members from Palmer College of Chiropractic, Walter Reed National Military Medical Center, Naval Hospital Pensacola, Naval Medical Center San Diego, Ft. Campbell Kentucky, Ft. Lewis Washington, and RAND Corporation attended.

The morning session, "Helping Your Patients to Quit Tobacco," included presentations and training on tobacco cessation by Judith Gordon, PhD, Associate Head for Research and Associate Professor at the University of Arizona, and Mitch Haas, DC, MA, Associate Vice President of Research at the University of Western States in Oregon. This presentation was targeted, specifically, to team members who will be conducting the ACT1 study. Drs. Gordon and Haas engaged the participants in a variety of activities and discussion to help them best assist patients in quitting tobacco use.

The afternoon session was attended by all investigators and doctors of chiropractic. This session offered the team the opportunity to become acquainted with one another and to share ideas and suggestions for implementing the studies. The session was led by Christine Goertz, DC, PhD, Vice Chancellor for Research and Health Policy at Palmer College of Chiropractic and Co-Principal Investigator of the project. Dr. Goertz presented details about each study and led discussions regarding communication amongst study team members. She also addressed potential barriers and concerns with rolling out the studies, recruitment issues, and retention of study subjects. Dr. Goertz shared with the team that Palmer will continue to utilize its expertise in managing the day-to-day conduct of each study and will work diligently to ensure the success and integrity of the project.

Site visits (ACT 1 TASK 7, ACT 2 TASK 1):

The following site visits were conducted over the past year:

- Naval Hospital, Pensacola, FL- Feb 29, 2012
- Madigan Army Medical Center, Ft. Lewis McChord, WA – May 15, 2012
- National Medical Center, San Diego - May 29, 2012
- Naval Hospital, Pensacola - July 9-12, 2012
- National Medical Center, San Diego – Sept. 10-14, 2012
- National Medical Center, San Diego – Nov. 2, 2012

The following site visits occurred this quarter. Summaries are provided below:

Naval Hospital, Pensacola – December 10-12, 2012

Dr. Katie Pohlman and Ms. Bridget Kane (newly hired Project Manager for Walter Reed National Military Medical Center) met with the Pensacola Site Project Manager, Ms. Sharon Phillips. The aim of this visit was to train Ms. Kane and to provide quality assurance and fidelity oversight for the recruitment and intake of study participants at Pensacola. The site PI, CDR Penta, and site Co-I/DC, Dr. Greg Lillie both met with study staff on several occasions throughout this visit.

Blanchfield Army Community Hospital, Ft. Campbell – December 13, 2012

Dr. Katie Pohlman met with site PI, Dr. Thomas Jones and SOF LCDR Helwig to discuss the logistics and finalize the study protocol for the ACT2 study at this site. This meeting had an hour teleconference with Co-PI Dr. Christine Goertz, Co-I Dr. James DeVocht, and study consultant Dr. Dean Smith. Another site visit was planned to be on January 24, which would allow a visit to the specific planned location of the study.

National Medical Center, San Diego – December 18-20, 2012

Dr. Katie Pohlman and Ms. Lara Hilton (Project Manager at RAND) and Ms. Bridget Kane (newly hired Project Manager for Walter Reed National Military Medical Center) met with the San Diego Site Project Manager, Ms. Amy Engel. The aim of the visit was to train Ms. Kane and to provide quality assurance and fidelity oversight for the recruitment and intake of study participants at San Diego. Dr. Ward met briefly with study staff. A tour of the facility was provided to Ms. Hilton.

Naval Hospital, Pensacola – January 7-9; 14-16; 22-23; 29-31; February 5-8; 11-13, 2013

Dr. Katie Pohlman and Ms. Bridget Kane were at the Naval Hospital, Pensacola site on the above dates as substitute site project managers. This allowed the study to continue to recruit participant and kept the corpsman and medical care providers aware of the study requirements. In addition quality assurance and fidelity oversight for the recruitment and intake of study participants also occurred. Each visit included several visits with site PI, CDR Penta, and site Co-I/DC, Dr. Greg Lillie.

National Medical Center, San Diego – January 24-25, 2013

On Jan. 24th, Dr. Christine Goertz met with the San Diego Site PI at the American Physical Therapy Association and discussed logistics of the study. Dr. Goertz also attempted to meet with ACT3 site PI, MAJ Rhon; however, this meeting was changed due to travel change. MAJ Rhon and Dr. Goertz scheduled a phone call for the following week. On Jan. 25th, Dr. Goertz met with San Diego Site Project Manager, Ms. Amy Engel. Together they met with the Co of the Coronado Health Clinic, CDR Chisholm. CDR Chisholm was a genuinely interested in the success of the study and presented the idea of using the Independent Duty Corpsmen (IDC) as the Conventional Medical Care providers. The IDCs are highly trained medical providers that are there to ensure all military personnel have an appointment within 24 hours. The next meeting was with the SMART provider. This meeting also was successful in that it provided the SMART clinic doctors with more information about the study and demonstrated ways that they could recruit participants into the study.

Naval Hospital, Pensacola – February 1, 2013

Dr. Christine Goertz presented “Translational Research in Manual Medicine” to the NHBC branch healthcare providers. This presentation was worth 1 CEU for all in attendance. Dr. Goertz also met with newly hired Site Project Manager, Wendy Freiberger. Together they discussed the study and Dr. Goertz introduced Ms. Freiberger to study personnel at the site.

Personnel Hire:

The Pensacola Project Manager Position was filled by Sharon Phillips, who was hired on February 20, 2012. Ms. Phillips successfully set up the processes at Pensacola for recruitment and started the study on Oct. 02, 2012. She resigned from the position as her immediate family needed assistance in St. Louis, MO on Jan. 8, 2013. The site Project Manager position was posted on Dec. 23, 2012. And the new Project Manager, Ms. Wendy Freiberger, was hired on January 31, 2013.

The San Diego Project Manager position was posted on Feb. 29 and Ms. Amy Engle accepted the position and began work on June 18, 2012. Ms. Engel successfully set up the processes at San Diego for recruitment and started the study on Sept. 11, 2012.

The Walter Reed National Military Medical Center Project Manager position was posted on May 7, 2012. After a lengthy recruitment process, Ms. Bridget Kane accepted the position on November 30, 2012. She has been training since being hired, as well as continuing recruitment at the Naval Hospital in Pensacola. Recruitment is anticipated to start at this site on March 11, 2013.

Regulatory Updates (ACT 1, TASK 3, ACT 2 TASK 3, ACT 3 TASK 2:

CRADA

The multi-party CRADA initiated by Mr. Alan Cash, WRNMMC ORTA, was reviewed and approved the second quarter of this reporting period. It received official signatures from: WRNMMC, Samueli Institute, Palmer College of Chiropractic and RAND Corporation and San Diego Commanding Admiral, who signed on behalf of NMCS and NHP. CRADA was officially completed on July 13, 2012.

The Army and Navy CRADA amendments are in process to include ACT 2 and ACT 3 statements of work and sites. The Navy CRADA amendment was forwarded to Mr. Alan

Cash, WRNMMC ORTA, on January 16, 2013 for review. Once an IT Impact Statement is obtained from WRNMMC the amendment will be sent for legal review.

Samueli Institute is in the process of amending their Master CRADA with the Army to include ACT 2 and ACT 3 for the Army hospitals at Fort Campbell and Fort Lewis. The amendment process was initiated January 16, 2013 with CIRO (Clinical Investigative Regulatory Office). Due to the grant's funding source, the Office of Congressionally Directed Medical Research Program under USA Medical Research and Material Command, the CRADA amendment will be reviewed by HRPO (Human Research Protection Office versus CIRO. The request was forwarded to Mr. Brian Garland, HRPO, January 29, 2013. On February 27, 2013, the project was assigned to Julie Welberding, HRPO reviewer for the final review of the protocol and Master CRADA.

IRB

ACT 1: Throughout the past year, this study gained approval from 5 IRBs (RAND, Palmer, NMCP, NMCSO, WRNMMC), as well as a signed DSAA with WRNMMC. All of the IRBs have successfully completed their continuing review. As the trial moves forward with recruitment at the three sites, various procedural site-specific issues arise which affect the protocols. Therefore, the version of the protocol that is currently underway is Version 12. This is planned to loop through all 5 of IRB reviews beginning in March.

An unrelated SAE was incidentally found by the site project manager on January 23, 2013 when seeking to collect the week 6 missed outcome measures. This event involved a participant that was allocated to the conventional medical care and chiropractic care group for low back pain on October 18, 2012. At the participant's first visit with the study doctor of chiropractic on October 25, 2012, the participant was determined ineligible for care due to pain potentially being caused by visceral source. No study care was received and the participant sought care from other healthcare providers outside the study that led to a cholecystectomy in early January 2013. Both Palmer and RAND's IRBs have reviewed this SAE and determined that no further changes are necessary. This report will be sent to the DSMC with their bi-annual review.

ACT 2: This study had a pilot component that was a reaction/response feasibility cohort study used to test the procedures for measurement and did not involve the use of chiropractic manipulation. It was approved by RAND on May 10, 2012 and Palmer IRB on May 23, 2012 and was conducted at Palmer from June 2012-February 2013. After it was found the measurement tools and protocols were feasible, ACT 2 went into full study IRB review. Palmer approved the study on May 1, and an amendment on June 14, 2012 and RAND approved it on September 18, 2012 with contingencies that were met on December 6, 2012 for full approval. The full study was approved by RAND and Palmer and is anticipated to be submitted to Dwight Eisenhower's IRB in March 2013.

ACT3: The ACT3 protocol was reviewed and accepted by Palmer's IRB on August 15, 2013. A feasibility study for ACT 3 was designed to take place at Palmer to test feasibility of the biomechanical tests and sham intervention on students with low back pain. This pilot study was approved by Palmer on January 11, 2013. It is currently under review at RAND IRB. After the approval of the ACT3 pilot study, the full ACT3 study will be sent to RAND's IRB. The study application will be sent to Ft. Lewis's IRB after RAND's approval have been received.

ACT Newsletter (ACT 1, 2, 3, PROJECT MANAGEMENT):

The ACT newsletter entitled "Back to ACTION" continued to be produced this year. Each newsletter includes a message from one of the Co-Principal Investigators or Project Managers, highlights from recent events, spotlights on a team member and information on upcoming events.

In the last year, the project staff continued to produce and email to constituents the newsletter with summary of newsletter activities as follows:

- February 2012: Message from Principal Investigator Joan Walter; Spotlight on Kimberly McConnell; Highlights on IRB approval process
- March 2012: Message from Principal Investigator Christine Goertz; Spotlight on Sharon Phillips; Highlights on ACT Team Meeting in Las Vegas.
- May 2012: Message from Principal Investigator Ian Coulter; Spotlight on CDR Joseph Penta; Highlights on Naval Hospital Pensacola.
- August 2012: Message from Dr. Christine Goertz; Spotlight on San Diego Project Manager, Amy Engel; Highlights on NMCSO
- September 2012: Message from Christine Goertz; Spotlight on Team Member: Project Manager Amy Engel in San Diego, Highlights on Naval Air Station North Island.
- February 2013: Message from Joan Walter; Spotlight on San Diego Principal Investigator, CDR Rosenthal, Highlights on the start of recruitment at Naval Medical Center San Diego and Naval Hospital Pensacola
- May 2013: Message from Ian Coulter; Spotlights on Site PMs, Ms. Wendy Freiburger and Ms. Bridget Kane; Highlights on WRNMMC

Budgeting issues (ACT 1, 2, 3 BUDGETS):

On November 9, 2012, Drs. Coulter and Goertz held a conference call with project officer Miriam Darnell to discuss the budget of the project. While the current budget is under the rate of the draw down expected at this point in the project this is a result of the fact that the IRB process has seriously delayed the beginning of the trials. However, the funds expended so far in trying to secure both the IRBs and the CRADA far exceeds what was budgeted for the study. The concern is that later in the project we will have insufficient funding.

Study site location changes:

Since project inception, the following changes have been made regarding site location: 1) ACT 2 was originally set to occur at Naval Medical Center San Diego, Ft. Lewis, and Ft. Campbell. However, due to changes in personnel at each of the bases, the decision has been made to conduct this study primarily at Ft Campbell, where we have strong Command support. We may also still collect some ACT 2 data (50 participants) at the Naval Medical Center in San Diego if we can confirm that this is feasible. Due to changes in deployment patterns, it was determined that we no longer had support to conduct a study in Special Operations Forces at Ft. Lewis. 2) Again due to personnel changes it has been determined that Ft Lewis is the best site to conduct ACT 3 and have moved this study there from Walter Reed National Military Medical Center. Finally, we have dropped one military site, US Army Health Clinic at Rock Island Arsenal in Illinois from inclusion in ACT 1. This site is located in close proximity to Palmer College of Chiropractic and was originally intended to be a pilot site to test web data collection systems. However, Rock Island Arsenal fell under the IRB for Walter Reed National Naval Medical Center, Bethesda during the structural changeover to the new Walter Reed National Military Medical Center (WRNMMC), Bethesda, MD. Due to this move, IRB applications were not accepted during the changeover period. In the interest of getting the program up and running, and in the face of multiple delays, we opted to begin recruitment at the 2 sites whose approvals moved along more expeditiously (Naval Medical Hospital Pensacola and Naval Medical Center San Diego) and troubleshoot the web collection system as needed during early recruitment at those sites.

Work for the next reporting period will include the following tasks:

- Begin recruitment at Walter Reed National Military Medical Center for ACT 1.
- Hire Site Project Managers for Ft. Lewis and Ft. Campbell.
- Hire part-time DC for Ft. Lewis
- Obtain final IRB approvals for ACT 2 and begin recruitment.
- Obtain IRB approvals for ACT3 pilot and full study protocols from RAND, then move into site IRB process.
- The ACT newsletter will continue to be produced and disseminated.

The work is collaboration between RAND Corporation, Palmer College of Chiropractic, and Samueli Institute.

KEY RESEARCH ACCOMPLISHMENTS:

Participant Recruitment and Enrollment (ACT 1 TASK 8):

As of February 18, 2013 the following recruitment has occurred:

ACT 1 Pensacola: 38 Allocated (3 enrolled into the Tobacco Cessation nested study)

ACT 1 San Diego: 25 Allocated (3 enrolled into the Tobacco Cessation nested study)

ACT 1 Walter Reed National Military Medical Center: Anticipated start date – March 11

REPORTABLE OUTCOMES:

Not applicable

CONCLUSION: Because of the considerable delays the project has encountered for both the IRB and CRADA processes, we do not have sufficient empirical data to report on at this moment. However, both ACT 1 and ACT 2 have been launched and ACT 1 is actively recruiting and enrolling patients. Act 2 is in the final stages of IRB review at military sites. While this is a complex project involving numerous sites across two service branches, the IRB process of which 5 sites have been completed, needs to be simplified if future studies such as this current effort are contemplated. This could be through the acceptance by all sites of one IRB of record. The lengthy IRB and CRADA process not only delays the implementation of the field study but also uses up resources needed for field work and analysis.

As chiropractic becomes firmly entrenched in military health services, the type of evidence produced by this study will enhance the performance of the chiropractors and be beneficial to personnel. This research will also examine the contribution of chiropractic care outside of simple musculoskeletal problems into preventive health care (smoking cessation) and optimal performance. The research, if positive, may support an expanded scope of practice for chiropractors in the military.

REFERENCES:

None to include.

APPENDICES:

None to include.

SUPPORTING DATA:

None to include.